



## General

### Guideline Title

Quality improvement guidelines for transhepatic arterial chemoembolization, embolization, and chemotherapeutic infusion for hepatic malignancy.

### Bibliographic Source(s)

Brown DB, Nikolic B, Covey AM, Nutting CW, Saad WE, Salem R, Sofocleous CT, Sze DY, Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for transhepatic arterial chemoembolization, embolization, and chemotherapeutic infusion for hepatic malignancy. *J Vasc Interv Radiol*. 2012 Mar;23(3):287-94. [105 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Brown DB, Cardella JF, Sacks D, Goldberg SN, Gervais DA, Rajan DK, Vedantham S, Miller DL, Brountzos EN, Grassi CJ, Towbin RB, SIR Standards of Practice Committee. Quality improvement guidelines for transhepatic arterial chemoembolization, embolization, and chemotherapeutic infusion for hepatic malignancy. *J Vasc Interv Radiol*. 2009 Jul;20(7 Suppl):S219-S226, S226.e1-10. [71 references]

## Recommendations

### Major Recommendations

#### Indications

##### General Indications

Chemoembolization is indicated in patients with liver-dominant hepatic malignancies who are not candidates for curative resection. All patients should undergo preprocedural imaging evaluation including some combination of contrast-enhanced computed tomography (CT), magnetic resonance (MR) imaging, and/or positron emission tomography/CT to ensure that disease is liver-dominant. Although limited treatment is possible in the setting of portal vein thrombosis, outcomes are optimized in the setting of a patent portal vein or with hepatopetal flow via collateral vessels. If there is a question of adequate portal perfusion at cross-sectional imaging, confirmation can be obtained at catheter angiography immediately preceding chemoembolization. Patient performance status should be determined during the preliminary interventional radiology clinic visit. Preprocedural evaluation also includes laboratory evaluation including complete blood count, prothrombin time, and evaluation of liver and kidney function. Exclusion criteria based on laboratory values are not definitively established. However, the constellation of more than 50% liver replacement with tumor, bilirubin level greater than 2 mg/dL, lactate dehydrogenase level greater than 425 mg/dL, and aspartate aminotransferase level greater than 100 IU/L has a strong anecdotal association with increased postprocedural mortality. Individual abnormalities of these four parameters have not been shown to predict adverse outcome from chemoembolization. Laboratory values and scoring systems have been used

differently by other authors. Commonly used scoring systems are outlined in Tables 1 to 3 in the original guideline document. A bilirubin cutoff value of 3 mg/dL has been described. The Child-Pugh scoring system is superior to the Model for End-stage Liver Disease system at predicting long-term survival in hepatocellular carcinoma (HCC). Patients with Child-Pugh class A disease or class B disease with an albumin level of at least 3.4 g/dL have improved survival. Another group found that Model for End-stage Liver Disease scores greater than 10 and Cancer of the Liver Italian Program scores greater than 2 were negative predictors of survival. The optimal scoring system to predict survival following therapy remains undefined, and investigation of novel predictors of outcome continues.

### *Hepatocellular Carcinoma*

Secondary to underlying cirrhosis, fewer than 20% of patients are candidates for surgical resection. Transplantation remains the only curative option for patients with HCC, and individuals with limited disease (i.e., one tumor <5 cm or three tumors <3 cm each) should be evaluated for transplantation during workup as part of a multidisciplinary effort. In potential transplant recipients, chemoembolization may decrease the drop-off rate from the transplant list and limit recurrence when a new organ has been obtained. Chemoembolization is being investigated for intrahepatic recurrence following transplantation as well. In limited experience, chemoembolization has been found to be effective in management of larger tumors and as adjuvant therapy for HCC resection.

Initial randomized trials evaluating chemoembolization versus symptomatic treatment had disappointing results. However, three well-constructed randomized trials have demonstrated significantly improved survival with chemoembolization. Poor outcomes from the initial trials can be directly linked to treatment of patients with advanced disease and to administration of excessive therapy. These outcomes reinforce the need to treat patients with well compensated cirrhosis and to repeat therapy in the setting of viable tumor on follow-up cross-sectional imaging. Many patients whose disease is treatable with chemoembolization may also be treatable with yttrium-90 as well. Patients with small tumors may also be considered for percutaneous ablative therapies, alone or in combination with chemoembolization. The choice between therapies should be based on the overall size, number, and location of the tumors.

Embolization for HCC has been demonstrated to be effective. Trials of drug-eluting beads loaded with doxorubicin and other agents are emerging. In a prospective, multicenter, randomized trial with a primary endpoint of tumor response at 6 months from treatment there was not a statistical difference between drug-eluting beads and oily chemoembolization. However, patients with limited hepatic reserve or performance status showed better outcomes with drug-eluting beads compared with chemoembolization. In a single-center prospective randomized trial treatment with drug-eluting beads loaded with doxorubicin resulted in a statistically longer time to progression than bland embolization.

### *Neuroendocrine Malignancy*

Initial control of symptoms is usually performed with short- or long-acting somatostatin agents. Most patients with symptomatic disease from hormone production or bulk have diffuse metastases, a contraindication to surgery. The frequent presence of diffuse metastases also limits the number of patients who are candidates for percutaneous ablative therapies. Chemoembolization and embolization of patients with hepatic metastases from neuroendocrine tumors can result in durable elimination of hormonal symptoms. A number of patients with hormonally active liver metastases also have extrahepatic disease at the time of diagnosis. However, as treatment can still reduce or eliminate symptoms, treatment should not be withheld from these patients. Published experience with drug-eluting beads for this disease entity remains preliminary. Early results appear similar to those of other transarterial therapies.

### *Colorectal Carcinoma*

Fewer than 20% of patients with colorectal metastases are candidates for curative resection. Survival rates with systemic chemotherapy have improved, with mean survival approaching 2 years. Chemoembolization can provide palliation and is typically used as a salvage option following systemic therapy. There is evidence that patient survival is improved if patients have had one or two lines of therapy versus three or more. Preliminary data with drug-eluting beads have been accrued in registry format. Further validation of this technique is pending.

### *Metastatic Uveal Melanoma*

Metastatic uveal melanoma is rarely resectable, and a significant number of patients die of liver failure secondary to hepatic metastases. The optimal treatment is by immunoembolization, with other intraarterial regimens rarely achieving survival times exceeding 9 to 10 months.

### *Other Metastases*

Other tumors that may present with liver-dominant metastases include breast carcinoma and soft-tissue sarcomas, including gastrointestinal stromal tumors. These tumors have been successfully treated with chemoembolization or embolization. Patient survival appears to be improved compared with historical controls, although randomized prospective data are not available.

Participation by the radiologist in patient follow-up, both in the hospital and at imaging follow-up, is an integral part of chemoembolization and will

limit the incidence of postprocedural complications and ensure appropriate scheduling of follow-up therapy. Close follow-up with monitoring and management of the patient by the interventional radiologist is appropriate.

The indication for intraarterial treatment of hepatic malignancy is the presence of liver-dominant malignancy with adequately preserved hepatic function. The threshold for this indication is 95%. When fewer than 95% of procedures are for this indication, the department will review the process of patient selection.

#### Preprocedural Considerations

Hydration is essential with intravenous administration of 150–300 mL/h of normal saline solution. Other premedications include antiemetic agents and steroids. Many operators administer antibiotic coverage for Gram-negative enteric organisms, although this practice is not universal or prospectively proven to be beneficial for all patients. In patients without an intact sphincter of Oddi from previous surgery, sphincterotomy, or biliary drainage, the risk of infection following embolization is significantly increased. The risk of postembolization infection appears to be reduced by prolonged pre- and posttreatment antibiotic therapy. The need for pretreatment bowel preparation is not definitive. In patients with carcinoid tumors, pretreatment with subcutaneous octreotide is important to limit carcinoid crisis caused by hormonal dumping from tumor necrosis after embolization.

#### Procedural Considerations

Given the frequency of variant hepatic arterial anatomy, initial angiography should include a study of the superior mesenteric and celiac arteries. Filming should be performed through the portal venous phase to ensure no change in the patency of the portal venous structures from preprocedure imaging. Practice patterns for level of catheter selection range from subsegmental to lobar embolization, depending on the type and number of tumors to be treated as well as the philosophy of the individual doing the procedure. Treatment of the entire liver in one session is associated with an increase in mortality. When treatment has led to permanent occlusion of the native hepatic arteries, several collateral pathways have been treated with clinical success, including the inferior phrenic, internal mammary and intercostal arteries. If these collateral arteries have potential communication with cutaneous vessels, embolization should be performed to limit the risk of cutaneous ischemic ulceration. Treatment should avoid the cystic artery if possible. If treatment of the tumor is not feasible without including the cystic artery in the infused area, chemoembolization may still be performed. The principal risk of treatment of the cystic artery is pain, which may potentially lengthen the posttreatment hospital stay but does not result in significant risk to the gallbladder itself. Intermittent infusion of 1% lidocaine between aliquots of the chemotherapy/Ethiodol slurry decreases postembolization pain.

#### *Oily Chemoembolization versus Embolization*

Randomized trials for treatment of HCC comparing protocols with and without chemotherapy are limited. A prospective randomized trial with three arms comparing survival with chemoembolization versus embolization versus symptomatic treatment showed a significant survival benefit for chemoembolization versus symptomatic treatment, and the trial was halted. At the time the trial was terminated, embolization without chemotherapy had shown similar survival to that associated with chemoembolization. The trial was not continued to determine whether embolization without chemotherapy would lead to a survival benefit versus symptomatic treatment alone. A separate metaanalysis did not reveal any clear-cut benefit from the addition of chemotherapy to embolization. A complicating factor in determining the gold-standard arterial infusion therapy is that chemotherapy regimens vary significantly from trial to trial. No ideal chemotherapeutic agent has been identified. A definitive statement regarding treatment with or without chemotherapy cannot be made without an adequately powered prospective trial.

#### *Oily Chemoembolization versus Chemotherapeutic Infusion*

Few comparisons of oily chemoembolization versus chemotherapeutic infusion techniques are available. Infusion without embolization appears to result in a lower percentage of tumor necrosis compared with chemoembolization, particularly in HCC greater than 3 cm in diameter. However, toxicity to the surrounding liver may be lower with infusion alone. Chemotherapeutic infusion may be considered an option in patients with severe hepatic dysfunction.

#### Postprocedural Considerations

Many practitioners recommend antibiotic treatment for 3 to 7 days following chemoembolization to cover Gram-negative enteric pathogens. Data regarding the need for routine antibiotic prophylaxis are mixed, without evidence of benefit. If a patient has a disrupted sphincter of Oddi, antibiotic treatment should be continued for approximately 2 weeks. Even with extended administration of antibiotics, data for this group of patients are limited, and the operator should proceed with caution in the setting of any biliary abnormality. Antibiotic treatment may be converted to oral administration as soon as patients can tolerate a normal diet, in order to facilitate expedient discharge. Ondansetron should be continued as long as needed. Narcotic agents should be available. One method preferred by many interventionalists to control pain is to administer narcotic agents via a patient-controlled analgesia pump.

### *Postprocedural Imaging*

Follow-up imaging should be performed 4 to 6 weeks after all tumor-bearing areas have been treated. If treatment of both lobes of the liver is planned, imaging between sessions may be performed based on operator preference. Signs of tumor necrosis on CT include ethiodized oil uptake and absence of arterial-phase enhancement when it was present before chemoembolization. Absent arterial enhancement when it was present before therapy is the principal determinant of tumor necrosis on MR imaging. There is a paucity of literature regarding postchemoembolization follow-up of lesions without arterial phase enhancement. Gross enlargement of a lesion or nodular enhancement in portal vein or delayed-phase imaging has been described as evidence of residual or recurrent tumor following radiofrequency ablation of lesions without initial arterial-phase enhancement. Similar findings may be present in the setting of residual or recurrent tumor following chemoembolization. Patients without active disease at follow-up should undergo follow-up imaging every 3 to 4 months.

### *Repeat Treatment*

Individuals with HCC or metastases from nonneuroendocrine tumors require further treatment when new or residual disease is detected. Patients with liver metastases from symptomatic neuroendocrine tumors should be treated again if the initial treatment does not result in symptomatic improvement or when symptoms recur. Before additional chemoembolization sessions, liver function test results and complete blood count should be rechecked to ensure the patient is still an appropriate candidate.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Hepatic malignancies, including hepatocellular carcinoma (HCC) and liver metastases

### Guideline Category

Evaluation

Management

Technology Assessment

Treatment

### Clinical Specialty

Gastroenterology

Internal Medicine

Oncology

Radiology

### Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To improve the quality of transhepatic arterial chemoembolization, embolization, and chemotherapeutic infusion for hepatic malignancy

## Target Population

Patients with liver-dominant neoplasms who are not candidates for curative resection

## Interventions and Practices Considered

1. Preprocedural considerations
  - Preprocedural contrast-enhanced computed tomography (CT), magnetic resonance (MR) imaging, and/or positron emission tomography/CT
  - Catheter angiography if necessary
  - Laboratory evaluation including complete blood count, prothrombin time, and evaluation of liver and kidney function
  - Use of various scoring systems
  - Hydration with intravenous normal saline solution
  - Premedication including antiemetics, steroids, and antibiotics, if indicated
  - Subcutaneous octreotide in patients with carcinoid tumors
2. Procedural considerations
  - Initial angiography including study of the superior mesenteric and celiac arteries
  - 1% lidocaine infusion if needed
  - Choosing the right procedure (chemoembolization, embolization, or chemotherapeutic infusion)
3. Postprocedural considerations
  - Antibiotics for 3 to 7 days after chemoembolization
  - Antiemetics (ondanestron)
  - Narcotic administration
  - Follow-up imaging
  - Repeat treatment if indicated

## Major Outcomes Considered

- Clinical success rates (defined as effective palliation with survival as the primary outcome)
- Complication rates

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

An in-depth literature search was performed by using electronic medical literature databases (mainly PubMed from 2006 to 2012 as the previous version was published in 2006). Articles from 2006 were searched to account for in-press publications not yet available on PubMed. Case reports were excluded in evaluation of oncologic efficacy and survival but were included when reporting on adverse events of importance. Larger sample sizes were used in general for studies evaluating more commonly treated tumors such as hepatocellular carcinoma (HCC) compared to less commonly reported tumors such as sarcoma. Search terms included *chemoembolization*, *chemoinfusion*, *embolization* alone and meshed with *hepatocellular carcinoma*, *colorectal cancer*, *neuroendocrine tumor*, *sarcoma*, and *melanoma* to uncover articles with appropriate selection criteria, sample size and reporting transparency.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Not stated

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

A critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, complication rates, outcomes, and thresholds for prompting quality assurance reviews.

## Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a modified Delphi consensus method. For the purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee members' practices, and, when available, the Society of Interventional Radiology (SIR) HI-IQ System national database.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

The draft document is critically reviewed by the Standards of Practice Committee members either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the Society of Interventional Radiology (SIR) membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee, and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Improved quality of transhepatic arterial chemoembolization, embolization, and chemotherapeutic infusion for hepatic malignancy

### Potential Harms

#### Complications

Complications occur in approximately 10% of patients. Use of drug-eluting beads is relatively new and toxicities related to this technique are evolving. Published complication rates and suggested thresholds include those in Table 5 in the original guideline document.

#### Major Complications of Hepatic Arterial Chemoembolization

- Liver failure
- Abscess with functional sphincter of Oddi
- Post-embolization syndrome requiring extended stay or readmission
- Abscess with biliary-enteric anastomosis/biliary stent/sphincterotomy
- Surgical cholecystitis
- Biloma requiring percutaneous drainage
- Pulmonary arterial oil embolus
- Gastrointestinal hemorrhage/ulceration
- Iatrogenic dissection preventing treatment
- Death within 30 days

Postembolization syndrome (fever, pain, increased white blood cell count) by itself is not considered a complication but an expected outcome of embolotherapy. A small percentage of patients will have prolonged symptoms requiring a greater level of postprocedure care.

## Contraindications

### Contraindications

Most patients with symptomatic disease from hormone production or bulk have diffuse metastases, a contraindication to surgery. The frequent presence of diffuse metastases also limits the number of patients who are candidates for percutaneous ablative therapies.

## Qualifying Statements

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The clinical practice guidelines of the Society of Interventional Radiology (SIR) attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

## Implementation of the Guideline

### Description of Implementation Strategy

An implementation strategy was not provided.

### Implementation Tools

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness



## IOM Domain

Effectiveness

Patient-centeredness

Safety

## Identifying Information and Availability

### Bibliographic Source(s)

Brown DB, Nikolic B, Covey AM, Nutting CW, Saad WE, Salem R, Sofocleous CT, Sze DY, Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for transhepatic arterial chemoembolization, embolization, and chemotherapeutic infusion for hepatic malignancy. J Vasc Interv Radiol. 2012 Mar;23(3):287-94. [105 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2009 Jul (revised 2012 Mar)

### Guideline Developer(s)

Society of Interventional Radiology - Medical Specialty Society

### Source(s) of Funding

Society of Interventional Radiology

### Guideline Committee

Society of Interventional Radiology Standards of Practice Committee

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### Financial Disclosures/Conflicts of Interest

D.B.B. is a paid consultant for Cook (Bloomington, Indiana) and Tengion (East Norriton, Pennsylvania). Constantinos T. Sofocleous is a paid consultant for SirTex (Lane Cove, Australia). A.M.C. is a paid consultant for PhaseRx (Seattle, Washington). Research has been funded by St. Jude Medical (Little Canada, Minnesota) and SirTex. None of the other authors have identified a conflict of interest.

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## Guideline Availability

Electronic copies: Available from the [Society of Interventional Radiology Web site](#) .

Print copies: Available from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

## Availability of Companion Documents

The following is available:

- Minimally invasive treatment for liver cancer. Video. Available from the [Society of Interventional Radiology Web site](#)

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## Patient Resources

The following is available:

- Interventional radiology treatments for liver cancer. Available from the [Society of Interventional Radiology Web site](#)

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